UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,941	02/26/2002	Brigitte Chau Phan	BTI2 100103502(USP2)USP7X1	7506

7590 03/25/2005

William P. Christie
CHRISTIE PARKER & HALE LLP
Post Office Box 7068
Pasadena, CA 91109-7068

EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,941	PHAN ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-115* is/are pending in the application.

4a) Of the above claim(s) *1-50 and 67-108* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Groups IIB, claims 51-66 in the reply filed on August 2, 2004 and applicant's election without traverse of species 13 (claims 52 and 53) filed on December 16, 2004 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 51-53 and 58-66 will be examined.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the inventor, KaYuen Yeung, changed his address without his initial.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 51-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Phan et al., (US 2003/0003464 A1, priority date: December 22, 2000).

The applied reference has three common inventors, Brigitte Phan, Jorma Virtanen, and Amethyst Lam, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 51, Phan *et al.,* teach an optical bio-disc, comprising a substrate having encoded information associated therewith, said encoded information being readable by a disc drive assembly to control rotation of the disc (see page 3, [0047] and [0048]); a target zone associated with said substrate, said target zone disposed at a predetermined location relative to said substrate and an active layer associated with said target zone (see page 4, [0052] and [0053]). Since Phan *et al.,* teach that capture layer comprising multiple identical DNA molecules each with an amino group is formed by covalently attaching the amino group to polystyrene-co-maleic anhydride (see page 4, [0053] and page 8, [0116]), Phan *et al.,* disclose a plurality of capture agents (ie., multiple identical DNA molecules) attached to said active layer so that when said substrate is rotated, said capture agents remain attached to said active layer to thereby maintain a number of said capture agents within said target zone so that when a dual bead complex including covalently bound probes is introduced into said target zone, said capture

agent sequesters said dual bead complex therein to thereby allow detection of captured dual bead complex.

Regarding claims 52 and 53, Phan *et al.*, teach that said capture agent is a single stranded oligonucleotide sequence (ie., RNA) as recited in claim 52 and said capture agent is a double stranded oligonucleotide sequence (ie., DNA) (see page 5, [0072]).

Regarding claims 58-60, Phan *et al.*, teach that said capture agent contains an amino group (ie., one of multiple identical DNA molecules with an amino group) as recited in claim 58 and said active layer is formed from a polystyrene-co-maleic anhydride wherein said amino group chemically reacts with said maleic anhydride to form a covalent bond thereby maintaining said capture agents within said target zone as recited in claims 59 and 60 (see page 4, [0053] and page 8, [0116]).

Regarding claims 61-64, Phan *et al.*, teach that said capture agent (ie., one of multiple identical DNA molecules with an amino group) binds with an anchor agent (ie., the transport probe) to thereby locate said anchor agent within said target zone as recited in claim 61 (see page 5, [0072]) wherein the anchor agent is bound to one of two beads forming said dual bead complex which includes a capture bead and a reporter bead, said anchor agent is associated with said capture bead, said anchor agent is associated with said reporter bead, and said capture and reporter beads are linked together by a target agent to thereby form said dual bead complex as recited in claims 62-65 (see pages 5, right column, page 6, left column, and Figures 7-11).

Regarding claim 66, Phan *et al.*, teach that said dual bead complex is immobilized within said target zone for inspection by an incident beam of electromagnetic radiation (ie., page 15, claim 50).

Therefore, Phan *et al.*, teach all limitations recited in claims 51-66.

5. Claims 51, 52, 58, and 61-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen (US Patent No. 6,342,349 B1, filed on July 21, 1998).

The applied reference has a common inventor, Jorma Virtanen, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 51, Virtanen teaches that an optical bio-disc comprising a substrate having encoded information associated therewith, said encoded information being readable by a disc drive assembly to control rotation of the disc (see column 9, lines 51-54 and Figure 11B); a target zone associated with said substrate, said target zone disposed at a predetermined location relative to said substrate, an active layer associated with said target zone; and a plurality of capture agents attached to said active layer (ie., locations on the disc having multiple identical oligonucleotides) so that when said substrate is rotated, said capture agents remain attached to said active layer to thereby maintain a number of said capture agents within said target zone (see column 8, lines 20-26, columns 16, lines 51-67 and column 17, lines 1-32, and Figure 2B). Since claim 51 does not require that a dual bead complex is on the optical bio-disc and the optical disc taught by Virtanen has an ability to bind to a dual bead complex when the dual bead

complex including covalently bound probes is introduced into said target zone and said capture agent sequesters said dual bead complex, claim 51 is anticipated by Virtanen.

Regarding claim 52, since Virtanen teaches that the oligonucleotide side members are adapted to bind complementary single strands of nucleic acids that may be present in a test sample (see column 16, lines 51-67), Virtanen discloses that said capture agent is a single stranded oligonucleotide sequence.

Regarding claim 58, Virtanen teaches that said capture agent (ie., the oligonucleotide) contains an amino group (see column 26, lines 45-58).

Regarding claims 61-66, since claim 51 does not require that a dual bead complex is on the optical bio-disc and claims 61-66 further limit claim 51, claims 61-66 are anticipated by Virtanen.

Therefore, Virtanen teaches all limitations recited in claims 51, 52, 58, and 61-66.

6. Claims 51, 52, 58, and 61-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Virtanen (WO 00/05582, published on February 3, 2000).

Regarding claim 51, Virtanen teaches that an optical bio-disc comprising a substrate having encoded information associated therewith, said encoded information being readable by a disc drive assembly to control rotation of the disc (see page 21, lines 10-13 and Figure 11B); a target zone associated with said substrate, said target zone disposed at a predetermined location relative to said substrate, an active layer associated with said target zone; and a plurality of capture agents attached to said active layer (ie., locations on the disc having multiple identical oligonucleotides) so that when said substrate is rotated, said capture agents remain attached to

said active layer to thereby maintain a number of said capture agents within said target zone (see page 17, lines 14-20, pages 37-39, and Figure 2B). Since claim 51 does not require that a dual bead complex is on the optical bio-disc and the optical disc taught by Virtanen has an ability to bind to a dual bead complex when the dual bead complex including covalently bound probes is introduced into said target zone and said capture agent sequesters said dual bead complex, claim 51 is anticipated by Virtanen.

Regarding claim 52, since Virtanen teaches that the oligonucleotide side members are adapted to bind complementary single strands of nucleic acids that may be present in a test sample (see page 37, lines 19-25), Virtanen discloses that said capture agent is a single stranded oligonucleotide sequence.

Regarding claim 58, Virtanen teaches that said capture agent (ie., the oligonucleotide) contains an amino group (see column page 60, first paragraph).

Regarding claims 61-66, since claim 51 does not require that a dual bead complex is on the optical bio-disc and claims 61-66 further limit claim 51, claims 61-66 are anticipated by Virtanen.

Therefore, Virtanen teaches all limitations recited in claims 51, 52, 58, and 61-66.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (1998 or 2000) as applied to claims 51, 52, 58, and 61-66 above, and further in view of Ward *et al.,* (US Patent No. 5,354,655, published on October 11, 1994).

The teachings of Virtanen have been summarized previously, *supra.*

Virtanen does not disclose that said capture agent is a double stranded oligonucleotide sequence.

Ward *et al.,* teach that a double stranded oligonucleotide sequence on a support hybridizes to a complementary probe after denatuation.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made an optical bio-disc recited in claim 53 wherein said capture agent is a double stranded oligonucleotide sequence in view of the prior art of Virtanen and Ward *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of oligonucleotide (ie., a single stranded oligonucleotide) from another kind of oligonucleotide (ie., a double stranded oligonucleotide) during the process of making an optical bio-disc recited in claim 53, in the absence of convincing

evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since either a single or double stranded oligonucleotide immobilized on a support has an ability to hybridizes to a complementary probe.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

9. Claims 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (1998 or 2000) as applied to claims 51, 52, 58, and 61-66 above, and further in view of Cohen *et al.,* (US 2002/0196435 A1, priority date: November 22, 2000).

The teachings of Virtanen have been summarized previously, *supra.*

Virtanen does not disclose that said active layer is formed from a polystyrene-co-maleic anhydride and said amino group chemically reacts with said maleic anhydride to form a covalent bond thereby maintaining said capture agents within said target zone as recited in claims 59 and 60.

Cohen *et al.,* teach that capture layer (ie., said active layer) in an optical disk is formed by a polystyrene-co-maleic Anhydride (see [0035]).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art

at the time the invention was made to have made an optical bio-disc recited in claims 59 and 60 wherein said active layer is formed from a polystyrene-co-maleic anhydride and said amino group chemically reacts with said maleic anhydride to form a covalent bond thereby maintaining said capture agents within said target zone view of the prior art of Virtanen and Cohen *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of capture layer (ie., a capture layer taught by Virtanen) from another kind of capture layer (ie., a capture layer taught by Cohen *et al.,*) during the process of making an optical bio-disc recited in claims 59 and 60, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since said capture agent (ie., the oligonucleotide) contains an amino group has an ability to attach a polystyrene-co-maleic anhydride.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
March 21, 2005

FRANK LU
PATENT EXAMINER